

REMARKS

In the Office Action dated August 15, 2006, claims 13-26 were examined. Claims 13-26 were rejected. In this response, no claims are amended and no claims are added. Reconsideration of the pending claims is requested in view of the following remarks.

I. Claims Rejected Under 35 U.S.C. § 103

A.

Claims 13-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over in view of U.S. Patent No. 6015804 issued to Golub ("*Golub*"). In order to establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the references when combined must teach or suggest all of the claim limitations. MPEP § 2142. Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

More particularly, the cited reference does not teach or suggest all of the claim limitations of independent claim 13. Claim 13 includes the limitation of: after the contacting, isolating the blood or fraction thereof having the increased cytokine receptors. *Golub* describes a method of enhancing endogenous interleukin-10 production in mammalian cells and tissues, which includes administering an effective amount of a tetracycline derivative. (Abstract) The isolating of the blood or fraction thereof having the increased cytokine receptors is not taught or suggested in *Golub* for at least the following reasons: (i) *Golub* describes a method for increasing cytokines whereas claim 13 describes a process for producing a composition which includes cytokine receptors, and (ii) *Golub* relates to cytokines (not cytokine receptors) whereas claim 13 describes a process for producing a composition including cytokine receptors. In *Golub*, there is no teaching or suggestion for a process to produce a composition. Moreover, *Golub* does not teach or suggest isolating the blood or the fraction thereof having the increased cytokine receptors.

In addition, there is no motivation in *Golub* to modify the reference to teach claim 13. *Golub* is concerned with enhancing the production of the *cytokine* IL-10. (col. 5, lns. 43-44) In contrast, claim 13 is directed to a process, which includes an increase in *cytokine receptors* as compared to the endogenous levels of cytokine receptors in a healthy mammal, which decreases the pathological conditions caused by an overproduction of cytokines. (see ¶ [0006]) In the

Summary of the Invention, for example, Applicants disclose “blood-derived compositions and methods of treating viral hemorrhagic diseases or disorders and other diseases involving a cytotoxic response in which . . . IL-1 . . . [is] elevated.” (¶ [0023]) In other words, Applicants disclose a technique for the *uptake of excessive cytokine*, while *Golub* is concerned with *enhancing cytokine production*. Thus, *Golub* actually teaches away from claim 13. Consequently, taking *Golub*, there would not be any reasonable expectation of success in isolating the blood or fraction thereof having the increased cytokine receptors, as disclosed in claim 13, because *Golub* actually teaches away from Applicants’ invention. In sum, there is no motivation to modify *Golub* to teach isolating a blood or a fraction thereof having increased cytokine receptors, as taught in claim 13, because *Golub* is directed to increasing cytokines, not cytokine receptors.

Furthermore, Applicants believe that the Examiner has not shown any motivation to modify *Golub* to teach isolating the blood or fraction thereof having the increased cytokine receptors. Assuming the reference to tetracyclines in *Golub* inherently increases the level of cytokine receptors, it does not follow that *Golub* provides any motivation for isolating blood having the increased cytokine receptors. In other words, if *Golub* does not recognize the inherent properties of tetracycline, as admitted by the Examiner’s argument, *Golub* cannot provide the motivation to isolate the blood with the increase cytokine receptors. Moreover, the isolation operations cited by the Examiner (examples 1 and 2 in *Golub*) also do not relate to isolation of the blood or fraction thereof for a composition for the treatment of a disease, condition or disorder. Instead, *Golub* describes culturing peripheral blood monocyte cells (PBMNC) and performing various experiments on the cells. (col. 9, lns. 25-27) Dependent claims 14-20 include all of the limitations of independent claim 13. Accordingly, Applicants respectfully submit that independent claim 13 and its respective dependent claims are patentably allowable in view of *Golub*.

Additionally, Applicants respectfully remind the Examiner that obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established. MPEP 2141.02(V). Applicants merely state this in response to the Examiner’s Response to Arguments and in no way admits that any aspect in Applicants’ claimed invention is inherent.

B.

Independent claim 21 includes the limitations of (i) contacting blood *in vivo* with a therapeutic substance selected from at least one of tetracyclines or tetracycline-like compounds thereby increasing the level of cytokine receptors in the blood at least three-fold; (ii) after the contacting, collecting a portion of the blood; and (iii) after the collecting, processing the portion of the blood to isolate a blood fraction comprising cytokine receptors. Thus, claim 21 is directed to a process for producing a composition. *Golub*, on the other hand, is directed to a method of treatment and does not teach or suggest the claim limitations of (a) after the contacting, collecting a portion of the blood or (b) after the collecting, processing the portion of the blood to isolate a blood fraction comprising cytokine receptors, as recited in claim 21. Moreover, there is no motivation to modify *Golub* to teach (a) collecting a portion of the blood or (b) processing the portion of the blood to isolate a blood fraction comprising cytokine receptors, as taught in claim 21, because *Golub* is directed to increasing *cytokines*, not increasing *cytokine receptors*. Thus, *Golub* actually teaches away from claim 21. Consequently, taking *Golub*, there would not be any reasonable expectation of success in (a) collecting a portion of the blood or (b) processing the portion of the blood to isolate a blood fraction comprising cytokine receptors, as disclosed in claim 21, because *Golub* actually teaches away from Applicants' invention. Dependent claims 22-25 include all of the limitations of independent claim 21. Accordingly, Applicants respectfully submit that the independent claim 21 and its respective dependent claims are patentably allowable in view of *Golub*.

II. Response to Examiner's Response to Arguments

On page 6 of the Office Action, the Examiner states that Applicant is "claiming a biological pathway." (Office Action, p.6) In response, Applicant states that the claims are directed to a process and not a biological pathway as can be noted in the preamble.

On page 6 of the Office Action, the Examiner states that the "method steps are already known." (Office Action, p.6) In response, Applicant states that the claims are directed to contacting blood with tetracycline or tetracycline-like derivative, then "harvesting" the blood, then processing the blood to be administered to treat certain diseases or conditions. These "method steps" are not known and the Examiner has not referenced any prior art to support his

position. If these "method steps" were indeed "known", then Applicant assumes that the Examiner would have made a rejection under the principle of anticipation (35 U.S.C. § 102) rather than obviousness (35 U.S.C. § 103), which he did not.

On pages 6-7 of the Office Action, the Examiner states that "Applicant also argues that Golub et al. does not recognize the inherent properties of tetracycline because the isolations operations as disclosed by Golub et al. do not relate to isolation of the blood or fraction thereof for a composition for the treatment of a disease, condition or disorder." (Office Action, pp. 6-7) In response, Applicant states that *Applicant* did not make this argument, but rather the *Examiner*; Applicant merely endorsed the Examiner's admitted statement in arguing that there is no motivation to modify *Golub* to teach Applicant's claims. Applicant restates its position as follows: "in other words, *if Golub* does not recognize the inherent properties of tetracycline, *as admitted by the Examiner's argument*, *Golub* cannot provide the motivation to isolate the blood with the increase cytokine receptors."

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 500-4787.

Respectfully submitted,

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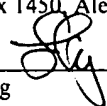

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